HFE-35 - NO pump

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEB - 1 2001

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Michael Golowski
President
Electrical Medical Systems, Incorporated
(Also d.b.a. Therapeutic Device Inc.)
39 Crescent Avenue
Trenton, New Jersey 08619-2555

Re: TENS Device, K894127

Dear Mr. Galowski:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your web site at the internet address http://www.electmed.com. Your web site promotes both a TENS device (Transcutaneous Electrical Nerve Stimulator) and an EMS unit (Electrical Muscle Stimulator), distributed by Electrical Medical Systems, Incorporated (EMS). The TENS device is manufactured by Lumiscope. The TENS and EMS are considered to be devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The product information and technical specifications page on your web site identifies your TENS unit as one that was cleared by FDA under K894127. The Lumiscope TENS device was cleared under section 510(k) of the Act and is intended for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post surgical and post traumatic acute pain problems.

Your web site makes claims for the TENS device that have not been cleared by the agency. Representative examples include, but are not limited to the following:

- Neck Pain and Headaches

  NOTE: Two of the contraindicaions for TENS devices identified in FDA's Guidance for TENS 510(k) Content dated August, 1994 (copy enclosed) specifically list the neck and pain of central origin as exclusions i.e., contraindicated for any electrode placement that applies current to the carotid sinus (neck) region; and, any electrode placement that causes current to flow transcerebrally (through the head).

- TENS not only helps the body get out of pain, but will also help the body get rid of the inflammation...(emphasis added)

- TENS units have been prescribed for pain resulting from a variety of conditions including ...pancreatitis,...TMJ (emphasis added)

The above claims represent a major modification in the intended use of the device as described under 21 CFR 807.81(a)(3)(ii) and require the submission of a new 510(k).

Continued promotion of your TENS device for claims of relieving neck pain, headaches, getting rid of inflammation, and use of TENS devices for treating pain resulting from pancreatitis, and/or TMJ causes your device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The TENS device is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

Additionally, we note that your web site under the EMS section claims that the EMS device can tighten, tone, and massage the body. FDA has not cleared any powered muscle stimulators with those claims. If Electrical Medical Systems has a 510(k) number for this device, please provide that 510(k) number. Even if you are using an EMS device that was cleared under a 510(k), the claims made on your web site would still cause the device to be misbranded and adulterated under the Act.

If your EMS device does not have a 510(k), then your electrical muscle stimulator (EMS) device is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

Your EMS device may also be misbranded under section 502(o) of the Act because the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510(k), was not included in a list required by section 510(j), and a notice or other information respecting the device was not provided to FDA as required by section 510(k).

This letter is not intended to be an all-inclusive list of deficiencies associated with your TENS and EMS devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We also note that your web site takes orders on line for both the TENS and EMS devices. We remind you that TENS and EMS devices are prescription devices as defined within the meaning of 21 CFR 801.109(d) and may not be sold without a valid prescription from a licensed practitioner. Additionally, the labeling for these devices must bear the following statement: "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New Jersey District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New Jersey District Office (HFR-MA300), 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054.

Sincerely yours,

Byron Tart for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure
Guidance for TENS 510(k) Content